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Mr. Stephen Johnson, Administrator
U.S. Environmental Protection Agency
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PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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Subject: Public Comments on the Trimethyl Phosphite Consortium's HPV Challenge Program Test Plan for Trimethyl Phosphite (CAS No. 121-45-9).

The following comments on the Trimethyl Phosphite Consortium's test plan for trimethyl phosphite (TMP) are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

Trimethyl phosphite is a chemical intermediate used in closed systems at chemical manufacturing sites and is typically fully reacted in the manufacture process. As a result, there is essentially no potential for repeat or public exposure.

We commend the Trimethyl Phosphite Consortium for its comprehensive review of existing data, in which it identified reliable data for either TMP or its hydrolysis product dimethyl phosphonate (DMHP) for all relevant SIDS endpoints with the exception of genotoxicity resulting from chromosomal aberration.

We are very concerned, however, that the consortium is proposing new *in vivo* genotoxicity testing, in clear contradiction to the principles laid out for the HPV Program in both the EPA's October 1999 letter to chemical sponsors and its December 2000 *Federal Register* notice on the program, which state that *in vivo* genotoxicity testing should be conducted only when known chemical properties preclude the use of *in vitro* testing. Since the consortium's test plan cites a total of nine *in vitro* genotoxicity tests, it is clear that TMP's chemical properties do not preclude their use.

An *in vitro* chromosomal aberration test, OECD 473, should be conducted – per the *Federal Register* instructions – rather than the *in vivo* micronucleus test which will cause the suffering and death of 80 animals. It is incumbent upon the consortium to conduct the *in vitro* chromosomal aberration test, since no chromosomal aberration tests were cited in the test plan.

In addition, a search of Syracuse Research Corporation's TSCATS database retrieved four studies which may also address the chromosomal aberration endpoint directly. The abstracts of these documents are attached, and we urge the

consortium and the EPA to further investigate whether these or other studies provide relevant existing data.

In summary, the proposed ***in vivo*** micronuclease test, OECD 474, is not justified. OECD 473, using human lymphocytes or an established cell line, should be used instead.

Thank you for your attention to these comments. I may be reached at 610-586-3975, or via e-mail at josephm@peta.org.

Sincerely,

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